Complete Summary

GUIDELINE TITLE

A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States. Recommendations of the Advisory Committee on Immunization Practices (ACIP) part 1: immunization of infants, children, and adolescents.

BIBLIOGRAPHIC SOURCE(S)

Mast EE, Margolis HS, Fiore AE, Brink EW, Goldstein ST, Wang SA, Moyer LA, Bell BP, Alter MJ. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP) part 1: immunization of infants, children, and adolescents. MMWR Recomm Rep 2005 Dec 23;54(RR-16):1-31. [21 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Hepatitis B virus infection

GUIDELINE CATEGORY

Management
Prevention

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Obstetrics and Gynecology
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Hospitals
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To improve prevention of perinatal and early childhood hepatitis B virus (HBV) transmission
- To update the immunization strategy to eliminate HBV transmission in the United States

TARGET POPULATION

- All infants in the United States including infants born to hepatitis B surface antigen (HBsAg)-positive women and women with unknown HBsAg status
- Children and adolescents who were not previously vaccinated
- Pregnant women who are at risk for hepatitis B virus (HBV) infection during pregnancy

INTERVENTIONS AND PRACTICES CONSIDERED

1. Routine prenatal hepatitis B surface antigen (HBsAg) testing of pregnant women
2. Vaccination of all infants (see the original guideline document for hepatitis B vaccine schedules)
    - Management of infants born to HBsAg-positive women
    - Management of infants born to women with unknown HBsAg status
    - Management of preterm infants (<2,000g)
3. Vaccination of pregnant women at risk of hepatitis B virus (HBV) infection
4. Vaccination of previously unvaccinated children and adolescents (see the original guideline document for hepatitis B vaccine schedules)
5. Postexposure prophylaxis

MAJOR OUTCOMES CONSIDERED

- Interpretation of serologic test results for hepatitis B virus (HBV) infection
- Sero-protection rates of single-antigen and combination vaccines

- Duration of immune memory
- Effectiveness of postexposure prophylaxis
- Side effects of hepatitis B vaccine

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Prevention of Perinatal Hepatitis B Virus (HBV) Infection and Management of Pregnant Women

Prenatal Hepatitis B Surface Antigen (HBsAg) Testing

- All pregnant women should be tested routinely for HBsAg during an early prenatal visit (e.g., first trimester) in each pregnancy, even if they have been previously vaccinated or tested.
- Women who were not screened prenatally, those who engage in behaviors that put them at high risk for infection (e.g., injection-drug use, having had more than one sex partner in the previous 6 months or an HBsAg-positive sex partner, evaluation or treatment for a sexually transmitted disease [STD], or recent or current injection-drug use) and those with clinical hepatitis should be tested at the time of admission to the hospital for delivery.
- All laboratories that provide HBsAg testing of pregnant women should use a U.S. Food and Drug Administration (FDA)-licensed or -approved HbsAg test and should perform testing according to the manufacturer's labeling, including testing of initially reactive specimens with a licensed neutralizing confirmatory test. When pregnant women are tested for HBsAg at the time of admission for delivery, shortened testing protocols may be used and initially reactive results reported to expedite administration of immunoprophylaxis to infants.
- Women who are HBsAg positive should be referred to an appropriate case-management program to ensure that their infants receive timely postexposure prophylaxis and follow-up (see Case-Management Programs to Prevent Perinatal HBV Infection in the "Description of the Implementation Strategy" field). In addition, a copy of the original laboratory report indicating the pregnant woman's HBsAg status should be provided to the hospital where delivery is planned and to the health-care provider who will care for the newborn.
- Women who are HBsAg positive should be provided with or referred for appropriate counseling and medical management (see Appendix A in the original guideline document). HBsAg-positive pregnant women should receive information concerning hepatitis B that discusses
    - modes of transmission
    - perinatal concerns (e.g., infants born to HBsAg positive mothers may be breast fed)
    - prevention of HBV transmission to contacts, including the importance of postexposure prophylaxis for the newborn infant and hepatitis B vaccination for household, sexual, and needle-sharing contacts
    - substance abuse treatment, if appropriate; and
    - medical evaluation and possible treatment of chronic hepatitis B

- When HBsAg testing of pregnant women is not feasible (i.e., in remote areas without access to a laboratory), all infants should receive hepatitis B vaccine ≤12 hours of birth and should complete the hepatitis B vaccine series according to a recommended schedule for infants born to HBsAg-positive mothers (see Tables 2 and 3 in the original guideline document).

Management of Infants Born to Women Who Are HBsAg Positive

- All infants born to HBsAg-positive women should receive single-antigen hepatitis B vaccine (see Table 2 in the original guideline document) and hepatitis B immune globulin (HBIG) (0.5 mL) ≤12 hours of birth, administered at different injection sites. The vaccine series should be completed according to a recommended schedule for infants born to HBsAg-positive mothers (see Table 3 in the original guideline document). The final dose in the vaccine series should not be administered before age 24 weeks (164 days).
- For preterm infants weighing <2,000 g, the initial vaccine dose (birth dose) should not be counted as part of the vaccine series because of the potentially reduced immunogenicity of hepatitis B vaccine in these infants; 3 additional doses of vaccine (for a total of 4 doses) should be administered beginning when the infant reaches age 1 month (see Tables 3 and 4 in the original guideline document).
- Postvaccination testing for anti-HBs and HBsAg should be performed after completion of the vaccine series, at age 9-18 months (generally at the next well-child visit). Testing should not be performed before age 9 months to avoid detection of anti-HBs from HBIG administered during infancy and to maximize the likelihood of detecting late HBV infection. Anti-HBc testing of infants is not recommended because passively acquired maternal anti-HBc might be detected in infants born to HBV-infected mothers to age 24 months.
    - HBsAg-negative infants with anti-HBs levels ≥10 mIU/mL are protected and need no further medical management.
    - HBsAg-negative infants with anti-HBs levels <10 mIU/mL should be revaccinated with a second 3-dose series and retested 1 to 2 months after the final dose of vaccine.
    - Infants who are HBsAg positive should receive appropriate follow-up (see Appendix A in the original guideline document).
- Infants of HBsAg-positive mothers may be breast fed beginning immediately after birth.
- Although not indicated in the manufacturer's package labeling, HBsAg-containing combination vaccines may be used for infants aged ≥6 weeks born to HbsAg-positive mothers to complete the vaccine series after receipt of a birth dose of single-antigen hepatitis B vaccine and HBIG.

Management of Infants Born to Women with Unknown HBsAg Status

- Women admitted for delivery without documentation of HBsAg test results should have blood drawn and tested as soon as possible after admission.
- While test results are pending, all infants born to women without documentation of HBsAg test results should receive the first dose of single-antigen hepatitis B vaccine (without HBIG) ≤12 hours of birth (see Tables 2 and 3 in the original guideline document).

    - If the mother is determined to be HBsAg positive, her infant should receive HBIG as soon as possible but no later than age 7 days, and the vaccine series should be completed according to a recommended schedule for infants born to HBsAg-positive mothers (see Table 3 in the original guideline document).
    - If the mother is determined to be HBsAg negative, the vaccine series should be completed according to a recommended schedule for infants born to HbsAg-negative mothers (see Table 3 in the original guideline document).
    - If the mother has never been tested to determine her HBsAg status, the vaccine series should be completed according to a recommended schedule for infants born to HBsAg-positive mothers (see Table 3 in the original guideline document). Administration of HBIG is not necessary for these infants.
- Because of the potentially decreased immunogenicity of vaccine in preterm infants weighing <2,000 g, these infants should receive both single-antigen hepatitis B vaccine and HBIG (0.5 mL) if the mother's HBsAg status cannot be determined ≤12 hours of birth. The birth dose of vaccine should not be counted as part of the 3 doses required to complete the vaccine series; 3 additional doses of vaccine (for a total of 4 doses) should be administered according to a recommended schedule on the basis of the mother's HBsAg test result (see Table 3 in the original guideline document).

Vaccination of Pregnant Women

- Pregnant women who are identified as being at risk for HBV infection during pregnancy (e.g., having more than one sex partner during the previous 6 months, been evaluated or treated for an STD, recent or current injection-drug use, or having had an HBsAg-positive sex partner) should be vaccinated.
- Pregnant women at risk for HBV infection during pregnancy should be counseled concerning other methods to prevent HBV infection.

Universal Vaccination of Infants

- All infants should receive the hepatitis B vaccine series as part of the recommended childhood immunization schedule (see Table 5 and Appendix B in the original guideline document). (For recommendations on management of infants born to HBsAg-positive mothers and infants born to mothers with unknown HBsAg status, see "Prevention of Perinatal HBV Infection and Management of Pregnant Women" section above.)
- For all medically stable infants weighing ≥2,000 g at birth and born to HBsAg-negative mothers, the first dose of vaccine should be administered before hospital discharge. Only single-antigen hepatitis B vaccine should be used for the birth dose.
- On a case-by-case basis and only in rare circumstances, the first dose may be delayed until after hospital discharge for an infant who weighs ≥2,000 g and whose mother is HBsAg negative.
    - When such a decision is made, a physician's order to withhold the birth dose and a copy of the original laboratory report indicating that the mother was HBsAg negative during this pregnancy should be placed in the infant's medical record.

    - For infants who do not receive a first dose before hospital discharge, the first dose should be administered no later than age 2 months.
    - Situations in which the birth dose should not be delayed include any high-risk sexual or drug-using practices of the infant's mother during pregnancy (e.g., having had more than one sex partner during the previous 6 months or an HBsAg-positive sex partner, evaluation or treatment for an STD, or recent or current injection-drug use) and expected poor compliance with follow-up to initiate the vaccine series.
- Preterm infants weighing <2,000 g and born to HBsAg-negative mothers should have their first vaccine dose delayed until 1 month after birth or hospital discharge (see Table 4 in the original guideline document). For these infants, a copy of the original laboratory report indicating that the mother was HBsAg-negative during this pregnancy should be placed in the infant's medical record.
- The vaccine series should be completed according to a recommended schedule with either single-antigen vaccine or a combination vaccine that contains the hepatitis B vaccine antigen (e.g., Haemophilus influenzae type b [Hib]-hepatitis B or diphtheria and tetanus toxoids and acellular pertussis adsorbed inactivated poliovirus [DtaP-IPV]-hepatitis B) (see Table 2 in the original guideline document). The final dose in the vaccine series should not be administered before age 24 weeks (164 days).
- Administration of 4 doses of hepatitis B vaccine to infants is permissible in certain situations (e.g., when combination vaccines are administered after the birth dose).
- In populations with currently or previously high rates of childhood HBV infection (i.e., Alaska Natives; Pacific Islanders; and immigrant families from Asia, Africa, and other regions with intermediate or high endemic rates of infection [see Figure 1 and Box 2 in the original guideline document]), the first dose of hepatitis B vaccine should be administered at birth and the final dose at age 6 to 12 months.

Vaccination of Children and Adolescents Who Were Not Previously Vaccinated

- Hepatitis B vaccination is recommended for all children and adolescents aged <19 years.
- Children and adolescents who have not previously received hepatitis B vaccine should be vaccinated routinely at any age with an appropriate dose and schedule (see Tables 2 and 5 in the original guideline document). Selection of a vaccine schedule should consider the need to achieve completion of the vaccine series. In all settings, vaccination should be initiated even though completion of the vaccine series might not be ensured.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Improved prevention of perinatal and early childhood hepatitis B virus (HBV) transmission
- Improved vaccine coverage of previously unvaccinated children and adolescents

POTENTIAL HARMS

Adverse Events of Hepatitis B Vaccine

- The most frequently reported side effects among persons receiving hepatitis B vaccine are pain at the injection site (3%-29%) and fever >99.9 degrees Fahrenheit (>37.7 degrees Celsius) (1%-6%). However, in placebo-controlled studies, these side effects were reported no more frequently among persons receiving hepatitis B vaccine than among persons receiving placebo.
- A causal association has been established between receipt of hepatitis B vaccine and anaphylaxis. On the basis of data from the Vaccine Safety Datalink (VSD) project, the estimated incidence of anaphylaxis among children and adolescents who received hepatitis B vaccine is one case per 1.1 million vaccine doses distributed (95% confidence interval = 0.1-3.9).
- Early postlicensure surveillance of adverse events suggested a possible association between Guillain-Barré syndrome and receipt of the first dose of plasma-derived hepatitis B vaccine among U.S. adults. However, in a subsequent analysis of Guillain-Barré syndrome cases reported to Centers for Disease Control and Prevention (CDC), U.S. Food and Drug Administration (FDA), and vaccine manufacturers, among an estimated 2.5 million adults who received $\geq$1 dose of recombinant hepatitis B vaccine during 1986-1990, the rate of Guillain-Barré syndrome occurring after hepatitis B vaccination did not exceed the background rate among unvaccinated persons. A review by persons with clinical expertise concluded that evidence was insufficient to reject or accept a causal association between Guillain-Barré syndrome and hepatitis B vaccination.
- Multiple sclerosis (MS) has not been reported after hepatitis B vaccination among children. However, one retrospective case-control study reported an association between hepatitis B vaccine and MS among adults. Multiple other studies have demonstrated no association between hepatitis B vaccine and MS. Reviews of these data by panels of persons with clinical expertise have favored rejection of a causal association between hepatitis B vaccination and MS.
- Chronic illnesses that have been reported in rare instances after hepatitis B vaccination include chronic fatigue syndrome, neurologic disorders (e.g., leukoencephalitis, optic neuritis, and transverse myelitis), rheumatoid arthritis, type 1 diabetes, and autoimmune disease. No evidence of a causal association between these conditions or other chronic illnesses and hepatitis B vaccine has been demonstrated.

- Reported episodes of alopecia (hair loss) after rechallenge with hepatitis B vaccine suggest that vaccination might, in rare cases, trigger episodes of alopecia. However, a population-based study determined no statistically significant association between alopecia and hepatitis B vaccine.

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindications and Precautions

- Hepatitis B vaccination is contraindicated for persons with a history of hypersensitivity to yeast or to any vaccine component. Despite a theoretic risk for allergic reaction to vaccination in persons with allergy to Saccharomyces cerevisiae (baker's yeast), no evidence exists that documents adverse reactions after vaccination of persons with a history of yeast allergy.
- Persons with a history of serious adverse events (e.g., anaphylaxis) after receipt of hepatitis B vaccine should not receive additional doses.
- As with other vaccines, vaccination of persons with moderate or severe acute illness, with or without fever, should be deferred until the illness resolves.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Prevention of Perinatal Hepatitis B Virus (HBV) Infection and Management of Pregnant Women

Delivery Hospital Policies and Procedures

- All delivery hospitals should implement policies and procedures (refer to Box 4 in the original guideline document) to ensure 1) identification of infants born to Hepatitis B surface antigen (HBsAg)-positive mothers and infants born to mothers with unknown HBsAg status (see Prenatal HBsAg Testing in the "Major Recommendations " field), and 2) initiation of immunization for these infants). Such policies and procedures should include the following standing orders:
    - for all pregnant women, review of HBsAg test results at the time of admission for delivery
    - for women who do not have a documented HbsAg test result, HBsAg testing as soon as possible after admission for delivery
    - identification and management of all infants born to HBsAg-positive mothers
    - identification and management of all infants born to mothers with unknown HBsAg status
    - for all infants, documentation on the infant's medical record of maternal HBsAg test results, infant hepatitis B vaccine administration, and administration of hepatitis B immune globulin (HBIG) (if appropriate)
- Delivery hospitals should enroll in the federally funded Vaccines for Children (VFC) program to obtain free hepatitis B vaccine for administration of the

birth dose to newborns who are eligible (i.e., Medicaid eligible, American Indian or Alaska Native, underinsured, or uninsured).

Case-Management Programs to Prevent Perinatal HBV Infection

- States and localities should establish case-management programs (refer to Box 5 in the original guideline document), including appropriate policies, procedures, laws, and regulations, to ensure that
    - all pregnant women are tested for HBsAg during each pregnancy, and
    - infants born to HBsAg-positive women and infants born to women with unknown HBsAg status receive recommended case management.
- The location of these programs and the methods by which they operate will depend on multiple factors (e.g., population density and annual caseload of HBsAg-positive women). Programs may be located in state or local health departments, private health-care systems (e.g., health maintenance organizations), or institutions (e.g., correctional facility systems). Program administrators will need to work with prenatal care providers, delivery hospital staff, pediatric care providers, private health-care systems, and health departments.

Universal Vaccination of Infants

- All delivery hospitals should implement standing orders for administration of hepatitis B vaccination as part of routine medical care of all medically stable infants weighing ≥2,000 g at birth (refer to Box 4 in the original guideline document).
- All delivery hospitals should implement policies and procedures for management of infants weighing <2,000 g at birth, including the following:
    - ensuring initiation of postexposure immunization of infants born to HBsAg-positive mothers and infants born to mothers not screened for HBsAg prenatally (see Prevention of Perinatal HBV Infection and Management of Pregnant Women in the "Major Recommendations" field), and
    - documentation of maternal HBsAg test results on the infant's medical record.
- Prenatal care education should include information regarding the rationale for and importance of newborn hepatitis B vaccination.
- States are encouraged to adopt regulations or laws that require hepatitis B vaccination for entry into child care and also for entry into kindergarten and/or elementary school to ensure high vaccine coverage among infants and children.

Vaccination of Children and Adolescents Who Were Not Previously Vaccinated

- To ensure high vaccination coverage among children and adolescents, the following measures are recommended:
    - All children aged 11-12 years should have a review of their immunization records and should complete the vaccine series if they were not previously vaccinated or were incompletely vaccinated.
    - All children and adolescents aged <19 years (including internationally adopted children) who were born in Asia, the Pacific Islands, Africa, or

other intermediate- or high-endemic countries (refer to Figure 1 and Box 2 in the original guideline document) or who have at least one parent who was born in one of these areas should have a review of their immunization records and should complete the vaccine series if they were not previously vaccinated or were incompletely vaccinated.
- States are encouraged to adopt regulations or laws that require hepatitis B vaccination before entry into middle school or its equivalent.
- Vaccination requirements should be considered for older high school students and for students before college entry, when feasible.
- States are encouraged to expand or implement immunization registries to include adolescents.
- Hepatitis B vaccine should be offered to all unvaccinated adolescents in settings that provide health-care services to this age group (refer to Box 6 in the original guideline document), particularly those who engage in behaviors that place them at high risk for HBV infection.

IMPLEMENTATION TOOLS

Staff Training/Competency Material

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Mast EE, Margolis HS, Fiore AE, Brink EW, Goldstein ST, Wang SA, Moyer LA, Bell BP, Alter MJ. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP) part 1: immunization of infants, children, and adolescents. MMWR Recomm Rep 2005 Dec 23;54(RR-16):1-31. [21 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Dec 23

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

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Advisory Committee on Immunization Practices ACIP Hepatitis Vaccines Working Group

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Centers for Disease Control and Prevention (CDC), their planners, and content experts wish to disclose they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters. Presentations will not include any discussion of the unlabeled use of a product or a product under investigational use.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site:

- HTML Format
- Portable Document Format (PDF)

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

Continuing Education activity is available from the Centers for Disease Control and Prevention (CDC) Web site.

PATIENT RESOURCES

None available

NGC STATUS

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